INDICATIONS

The Mentor® Artoura® Breast Tissue Expanders are indicated for temporary volume restoration of soft tissue defects. The Mentor® Artoura® Breast Tissue Expanders are for temporary volume restoration of soft tissue defects. The devices are intended for temporary subcutaneous or submuscular implantation and are not intended for use beyond six months. These tissue expanders can be used to treat mastectomy or trauma defects, postmastectomy reconstruction, augmentation mammaplasty, reconstruction following mastectomy or trauma, radiation therapy breast reconstruction, and revision and tissue defect procedures. The devices are intended for temporary subcutaneous or submuscular implantation and are not intended for use beyond six months.

Patient Instructions

The patient should be advised that vigorous body movement (e.g. physical exercise) or excessive manipulation or restriction may cause deflation. Leakage from the injection dome can result from the use of an improper size of injection needle, injections outside the injection dome, DO NOT ATTEMPT TO INJECT INTO THE AREA AROUND THE DOME, as device damage may still necessitate device replacement. Although the tissue expanders have a self-sealing BUFFERZONE which may prevent fluid leakage from the injection dome, DO NOT ATTEMPT TO INJECT INTO THE AREA AROUND THE DOME, as device damage may still necessitate device replacement. Although the tissue expanders have a self-sealing BUFFERZONE which may prevent fluid leakage from the injection dome, DO NOT ATTEMPT TO INJECT INTO THE AREA AROUND THE DOME, as device damage may still necessitate device replacement. 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### Fluid Accumulation

Dissatisfaction with cosmetic results

Deflation/Rupture/Leakage

Complications of Tissue Expansion

Capsule Formation and Contracture

- Excessive post-operative fluid accumulation and transient reaccumulation of fluid around the tissue expander as a result of trauma and after vigorous exercise have been reported.

The incidence of extrusion of the tissue expander has been shown to increase when the tissue expander has been preoperative assessment of stresses causing movement of the tissue expander.

- e.g. when the tissue expander is too large or the pocket is too small or when there has been inadequate volume.

Surgeons have reported that in some patients, visible or palpable wrinkling of the envelope, usually associated with wrinkled tissue, has occurred. Ensure that the expander can easily slide under the wrinkled skin without difficulty.

- Thrombosis, the breakdown of skin over the device and subsequent extrusion. Deflation or removal of the device may be necessary to prevent device extrusion.

- Contracture of the fibrous capsule may occur, independent of its thickness. Discomfort, pain, excessive tissue firmness and misshapen expanded tissue, deflation, increased palpability and wrinkling and/or displacement of the expanded tissue may occur and may require surgical intervention. In some patients, tissue firmness may recur after reduction of the area has been performed; and where steroids are used in the surgical pocket.

- Capsule formation and abdominal wall retraction have been reported as complications of tissue expansion. It is recommended that the device not be used until bleeding is controlled.

- To mark the injection, follow one of these options:
  - Option 1: Utilize a combination of options 1 and 2 for further confirmation of the best point for injection.
  - Option 2: With the magnetic arm centered in the target, make a mark with a surgical sterile marker in each of the three notches around the anterior perimeter of the base. Next, make a fourth mark in the hole located behind the magnetic arm that runs through the center base of the locator. After all four marks have been made, lift the device from the skin to create a smooth surface. With the free-swinging magnetic arm that runs through the center base of the locator, follow the direction that the arm points towards until the arm is pointing straight towards the hole in the base of locator (the injection area). This point is the injection site.
  - Option 3: A well-defined, dry pocket of adequate size and symmetry must be created to allow the expander to be placed flat on a smooth surface.

- The tissue expander should not be too small or too large in comparison to the patient’s chest wall dimensions.

- A well-defined, dry pocket of adequate size and symmetry must be created to allow the expander to be placed flat on a smooth surface.

- The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by the following steps:
  1. Using a 21 gauge standard needle, partially inflate the device with air through the injection dome.
  2. Submerge the air-filled expanders in sterile, pyrogen-free testing fluid (water or saline).
  3. Apply mild pressure and check for possible punctures or leaks.

- The device is returned to the manufacturer for examination and analysis.

- To mark the injection, follow one of these options:
  - Option 1: Utilize a combination of options 1 and 2 for further confirmation of the best point for injection.

- To inflate either tissue expander:
  - 2. Once the center of the dome has been identified, a skin marker can be used to identify the area of injection.
  - 3. If necessary, an incision can then be made and the device can be inserted through this incision. The device should be positioned so that the dome is oriented towards the intended side.

- To inflate either tissue expander:
  - 2. Once the center of the dome has been identified, a skin marker can be used to identify the area of injection.

- To inflate either tissue expander:
  - 3. If necessary, an incision can then be made and the device can be inserted through this incision. The device should be positioned so that the dome is oriented towards the intended side.

- To inflate either tissue expander:
  - 4. Injections must be made into the injection dome. If injections are made on the sides or outside the injection dome leakage can occur. Although the device has a self-sealing BUFFERZONE around the area of the injection dome, DO NOT infiltrate the device without expanding. This point is the injection site.

- To inflate either tissue expander:
  - 5. Make a mark with a surgical sterile marker in each of the three notches around the anterior perimeter of the base. Next, make a fourth mark in the hole located behind the magnetic arm that runs through the center base of the locator. After all four marks have been made, lift the device from the skin to create a smooth surface. With the free-swinging magnetic arm that runs through the center base of the locator, follow the direction that the arm points towards until the arm is pointing straight towards the hole in the base of locator (the injection area). This point is the injection site.

- To inflate either tissue expander:
  - 6. Injections must be made into the injection dome. If injections are made on the sides or outside the injection dome leakage can occur. Although the device has a self-sealing BUFFERZONE around the area of the injection dome, DO NOT infiltrate the device without expanding. This point is the injection site.